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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,062	04/30/2002	Thomas Moore	GK-OEH-120/500814.20021	7191

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EXAMINER

ALLEN, MARIANNE P

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 08/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/030,062

Applicant(s)

MOORE ET AL.

Examiner

Marianne P. Allen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-26 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 13-26 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/24/04 has been entered.

Abstract

The corrected abstract submitted 5/3/05 is noted.

Claim Rejections - 35 USC § 112

Claims 19-22 and 24-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 19-21 and 24-26 have been amended. No basis has been pointed to for these amendments and none is apparent. The specification does not appear to disclose $d \times 96$ well microtiter plates, where d is an integer > 0 . The specification does not appear to disclose assembling generic quantifiers and identifiers in a database nor the concept of "their positions resulting from the separation sequence." It is unclear if this phrase is with reference to the ordering of the analysis data within the database. Note that Figure 1 is a particular table and that

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the claims are not limited to such a table and this particular example does not provide basis for the presently claimed generic concept.

A fair reading of the originally filed specification does not readily convey to one of ordinary skill in the art what is now claimed.

Claims 13-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 is remains confusing in requiring that the M liquid fractions are identified by τ different analysis processes qualitatively yet never using this qualitative data in any way. Applicant argues on page 11 of the response that the qualitative analysis data are used as identifiers for characterizing the proteome. The claims do not set forth this concept.

Claim 25 is confusing in its dependency on claim 20 as it repeats the limitation set forth in claim 20.

Claim 26 is confusing in its dependency on claim 21 as it repeats the limitation set forth in claim 26.

Claim Rejections - 35 USC § 102

Claims 13-14, 16-19, 21, and 23-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Opiteck et al. (Analytical Biochemistry, May 1998).

Opiteck et al. discloses a method for multidimensional analysis of a proteome. The proteome is first separated according to size using size exclusion chromatography (SEC). In a

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second step the protein fractions obtained thereby are concentrated on an RP-HPLC column and separated from the elution liquid used for the SEC method. Next, the concentrated protein fractions are separated according to their hydrophobicity using a gradient elution. (Meeting the limitation of a third separating process or $n=3$.) The liquid fractions are quantitatively measured using UV-spectroscopy and the proteins obtained therefrom are identified by means of MALDO-TOF/MS, ESI/MS or sequencing. Following at least one separation step the fractions were deposited into 96-well microtiter plates. The compilation of the information meets the limitation of an n-dimensional image of the proteome and the saved data with respect to the proteome meets the limitation of a database as set forth in claim 24. See abstract and figures.

Applicant's arguments are unpersuasive. These arguments are with respect to limitations not present in the claims (i.e. online versus offline), functionalities not required by the claims (i.e. ability for control and adjustment after every separation step), and/or elements disclosed by the prior art that are not precluded by the claims.

Claims 13-18 and 23-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Blackstock et al. (TIBTECH, March 1999).

Applicant's response correctly notes that the examiner mistyped the first author's name for this reference.

Blackstock et al. discloses multidimensional analysis of a proteome comprising affinity separation followed by 2D gel electrophoresis. (Three separation processes.) Identification of proteins is by mass spectrometry. Information about the proteome is saved. See at least abstract and figures.

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Applicant's arguments are unpersuasive. These arguments are with respect to limitations not present in the claims, functionalities not required by the claims, or elements disclosed by the prior art that are not precluded by the claims (i.e. fractionation of tagged proteins). The separation processes of Blackstock et al. would be performed in liquid fractions.

Claims 13-14, 17, and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by Schneider et al. (U.S. Patent No. 6,677,114 B1).

Schneider et al. discloses and claims separating proteins based on at least three biophysical characteristics and then identifying them by mass spectrographic fragmentation. Fingerprint datasets from a sample are established. (See at least abstract, figures, claims (particularly claim 6), and columns 8-10.)

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 571-272-0712. The examiner can normally be reached on Monday-Thursday, 5:30 am - 1:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Marianne P. Allen

Marianne P. Allen
Primary Examiner
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7/29/05

mpa